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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,867	06/05/2006	Michael Horstmann	RO4244US (#90568)	3928

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D. PETER HOCHBERG CO. L.P.A.
1940 EAST 6TH STREET
CLEVELAND, OH 44114

EXAMINER	
BLIZZARD, CHRISTOPHER JAMES	
ART UNIT	PAPER NUMBER
3771	
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10/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,867	HORSTMANN ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER BLIZZARD	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 July 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to amendment filed 6/5/06. As directed by the amendment, claims 1, 15, 17, and 24 were amended, no claims were added, and claim 10 was cancelled. Thus, claims 19, and 11-30 are presently pending in this application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 11 recites the limitation "according to claim 10" in first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 5, 12, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Honeycutt (4,765,348).

6. Regarding claims 1, 2, 5, 12, 22 and 23, Honeycutt discloses a device for administration of nicotine to the human body by inhalation (column 1, lines 37-45) for

the purpose of being a non-combustible simulated cigarette (column 1, 8-10), wherein the device comprises a first preparation (18) containing a free base of nicotine (column 1, lines 45-46) contained in a polytetrafluoroethylene matrix (column 3, lines 11-18), and a second preparation (20) containing a volatile acid (column 1, lines 46-52), such as acetic acid (column 2, line 39) which is separated from the first preparation (18) by an impermeable partition (24) (column 2, lines 48-49). The device contains a first air inlet, located to the right of section 18 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #18 in figure 3, a second air inlet, located to the right of section 20 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #20 in figure 3, a common flow path (22) where the two airstreams from the separate sections combine simultaneously due to inhalation and an outlet aperture (16) where the common flow path leads to (column 2, lines 60-69).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3, 4, 9, 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348) in view of Ray (4,284,089).

9. Regarding claims 3, 4, 9, 24, 25 and 27 Honeycutt does not disclose the preparations containing a solvent suitable for inhalation. Ray teaches a preparation containing water as a solvent as well as menthol dissolved in ethanol as a flavoring

(column 4, lines 23-28; column 7, lines 14-22). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with solvents as taught by Ray in order to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

10. Claims 6, 7, 8, 14, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348)

11. Regarding claim 6, Honeycutt discloses the chemical balance between volatized nicotine and acid can be controlled (column 3, lines 1-10), but does not disclose the exact ratio of the chemical balance. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that during inhalation a ratio of equimolar quantities of the nicotine and acid could be released in order to provide the advantage of giving the vapor a neutral pH.

12. Regarding claims 7, 8, 14, 26 and 30, Honeycutt discloses the claimed invention except for the inspiration duration, velocity, nicotine dose, particle size, and negative pressure differential. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with appropriate size elements to create airflows and chemical balances necessary to operate the device successfully (column 3, lines 1-10), since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

13. Regarding claim 28 and 29, Honeycutt discloses the device having an impermeable part (24) (column 2, lines 48-49) as well as discloses that the device can

be made of any material (column 2, lines 11-13), but does not disclose a definite composition of the whole device. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the entire device out of the impermeable material of impermeable partition (24) and for this material to be a polyester material coated with a copolymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

14. Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348) in view of Turner (5,400,808).

15. Regarding claim 29, Honeycutt does not disclose the material which is impermeable. Turner teaches a nicotine impermeable container constructed of aluminum foil coated with a copolymer of acrylonitrile and methyl acrylate (column 2, lines 36-41). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt a material as taught by Turner in order to provide the advantage a longer shelf life of the contents of the inhaler.

16. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348) in view of Ferre (726,037).

17. Regarding claim 13, Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. Ferre teaches an inhaler with separate impermeable (lines 53-54) compartments (a, c) that have orifices (f) that can be opened or closed (line 70). Therefore it would have

been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with a sealable compartments as taught by Ferre, and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive disposable sealing means.

18. Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348) in view of Kallstrand (5,660,169).

19. Regarding claims 15-21 Honeycutt discloses the claimed invention except for a part formed by deep-drawing. Kallstrand discloses an inhaler device with an upper (1) and bottom part (2), containing a compartment with a peelable seal (figs. 3a-c), formed by deep-drawing (column 2, lines 11-14). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the inhaler of Honeycutt with deep-drawn components as taught by Kallstrand in order to provide the advantage of an inexpensive way to manufacture the device.

Response to Arguments

20. Applicant's arguments filed 7/20/09 have been fully considered but they are not persuasive. Applicant's arguments concerning the polymer matrix of Honeycutt not containing a nicotine-base preparation or acid-containing preparation in a dissolved or dispersed is not persuasive because the it does contain a nicotine-base preparation or acid-containing preparation that is dissolved in a solvent and/or is dispersed within the matrix.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771
/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771